EXHIBIT C

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs, v. ZYDUS PHARMACEUTICALS USA INC. and CADILA HEALTHCARE LIMITED, Defendants.	CIVIL ACTION NO: 3:10-CV-01723-JAP-TJB **TO BE FILED UNDER SEAL CONTAINS HIGHLY CONFIDENTIAL-ATTORNEYS' EYES ONLY INFORMATION**

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE EXPERT TESTIMONY BY JAMES MORRISON

HIGHLY CONFIDENTIAL-ATTORNEYS' EYES ONLY

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CASES

Pursuant to the Court's February 20, 2013 Order establishing deadlines for the submission of Pretrial Motions, Defendants Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (collectively "Zydus") respectfully submit this Memorandum of Law in Opposition to Plaintiffs' February 28, 2013 Motion *In Limine* to Preclude Expert Testimony by James Morrison. In addition to this Memorandum of Law, Zydus relies on the March 6, 2013 Declaration of Vincent P. Rao, II ("Rao. Decl.") and the exhibits attached thereto.

SUMMARY OF THE ARGUMENT

Plaintiffs move *in limine* for an order precluding the testimony of Zydus's expert witness James Morrison ("Morrison"). Plaintiffs offer several reasons for precluding Morrison's testimony, but the gravamen of Plaintiffs' motion *in limine* is that the opinions and testimony Morrison will offer is irrelevant. In fact, Morrison's testimony is relevant and should not be excluded.

Plaintiffs' argue that Morrison is not qualified as an expert because he is not a person of ordinary skill in the art, but that argument misses the point. Zydus does not contend that Morrison is qualified to testify on the intricacies of the chemistry underlying the product at issue, or even that he would qualify as a person of ordinary skill in the art for purposes of patent invalidity.

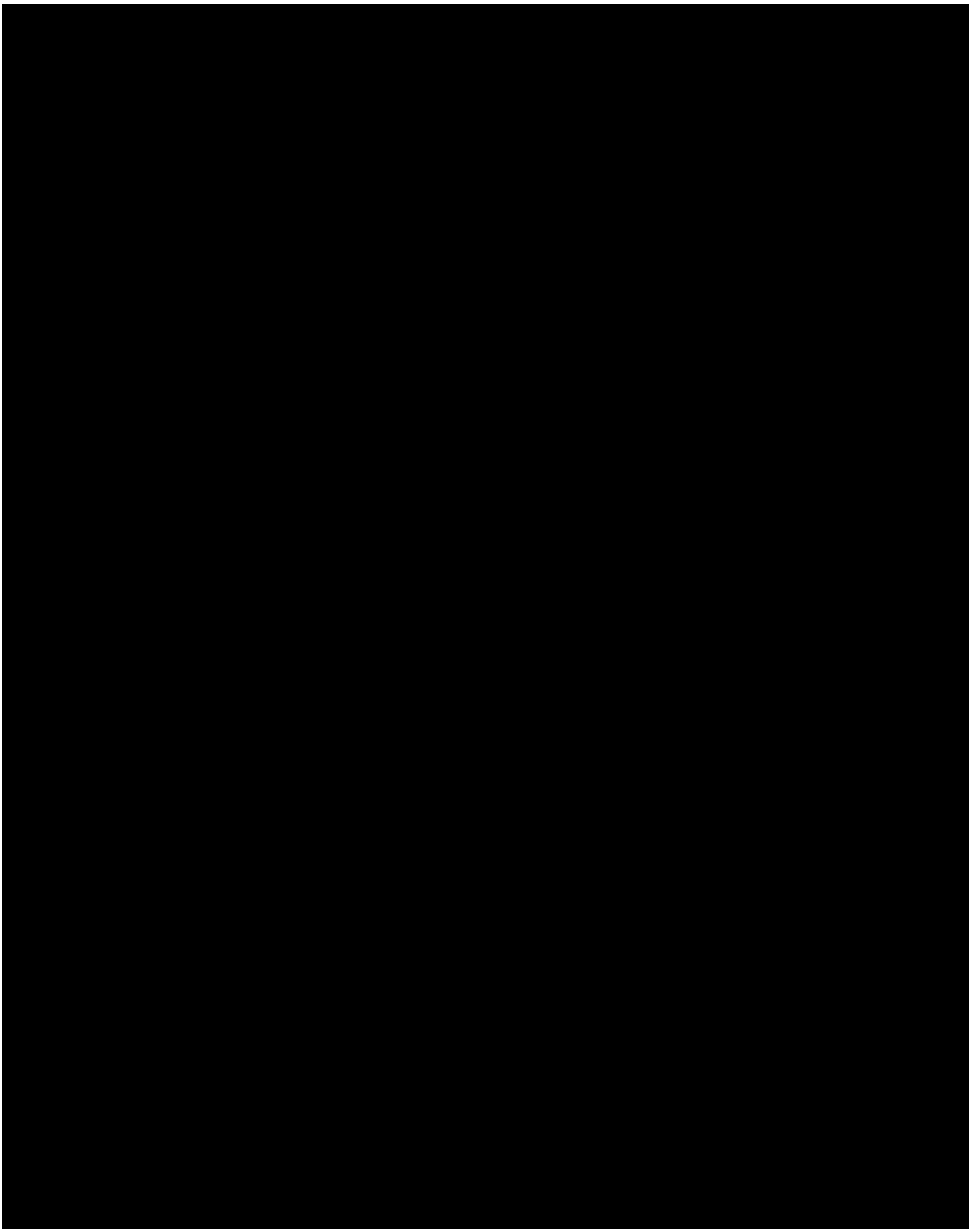
Zydus intends to proffer Morrison to testify about the expectations of the Federal Food and Drug Administration ("FDA") [redacted]

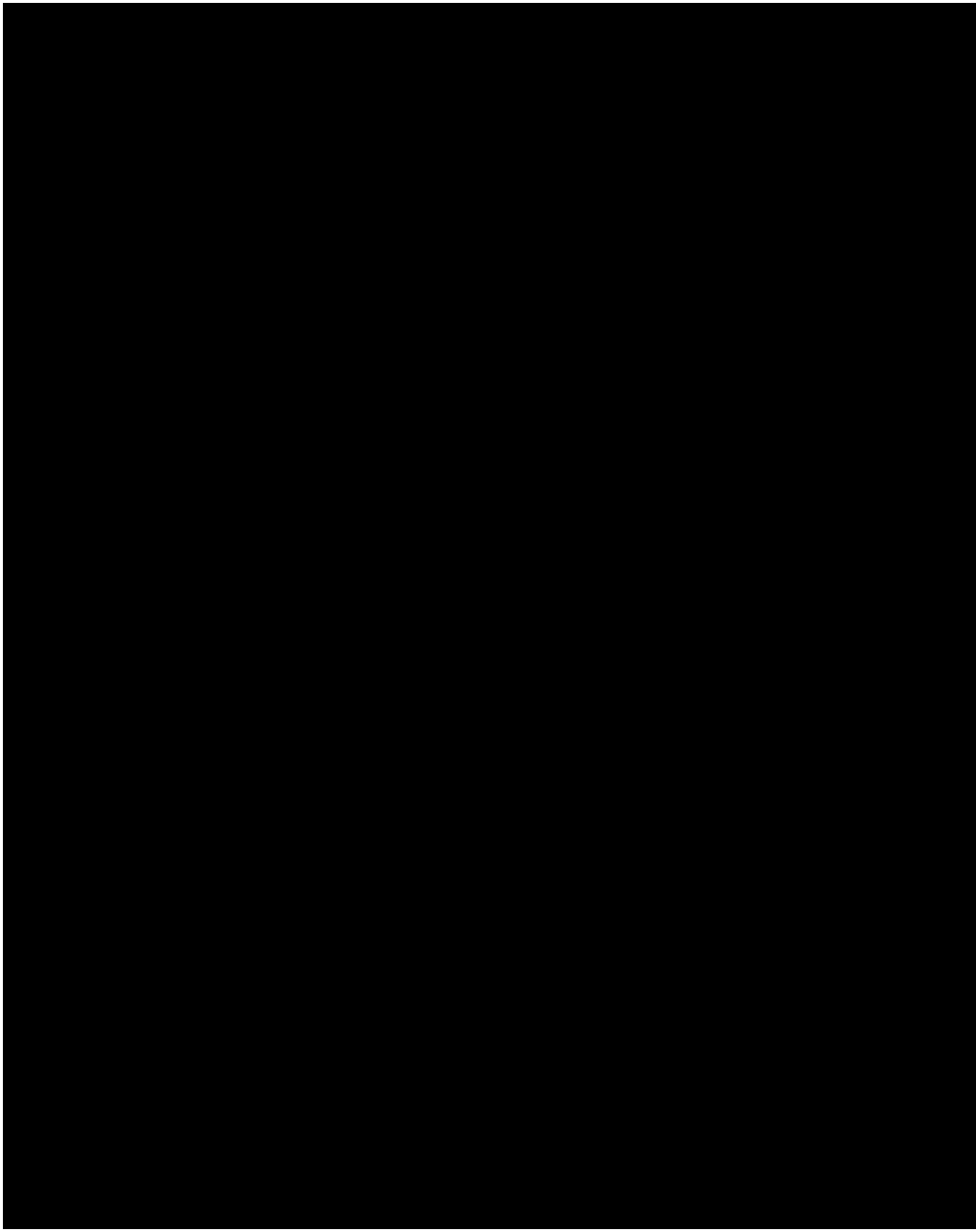
[redacted] and whether the FDA would accept certain of the conclusions reached by Plaintiffs' infringement expert, [redacted]. Morrison is qualified to testify about these FDA matters; Plaintiffs' do not argue to the contrary. Thus, Plaintiffs' motion *in limine* should be denied, and Morrison should be permitted to testify on all matters within the purview of his stated expertise.

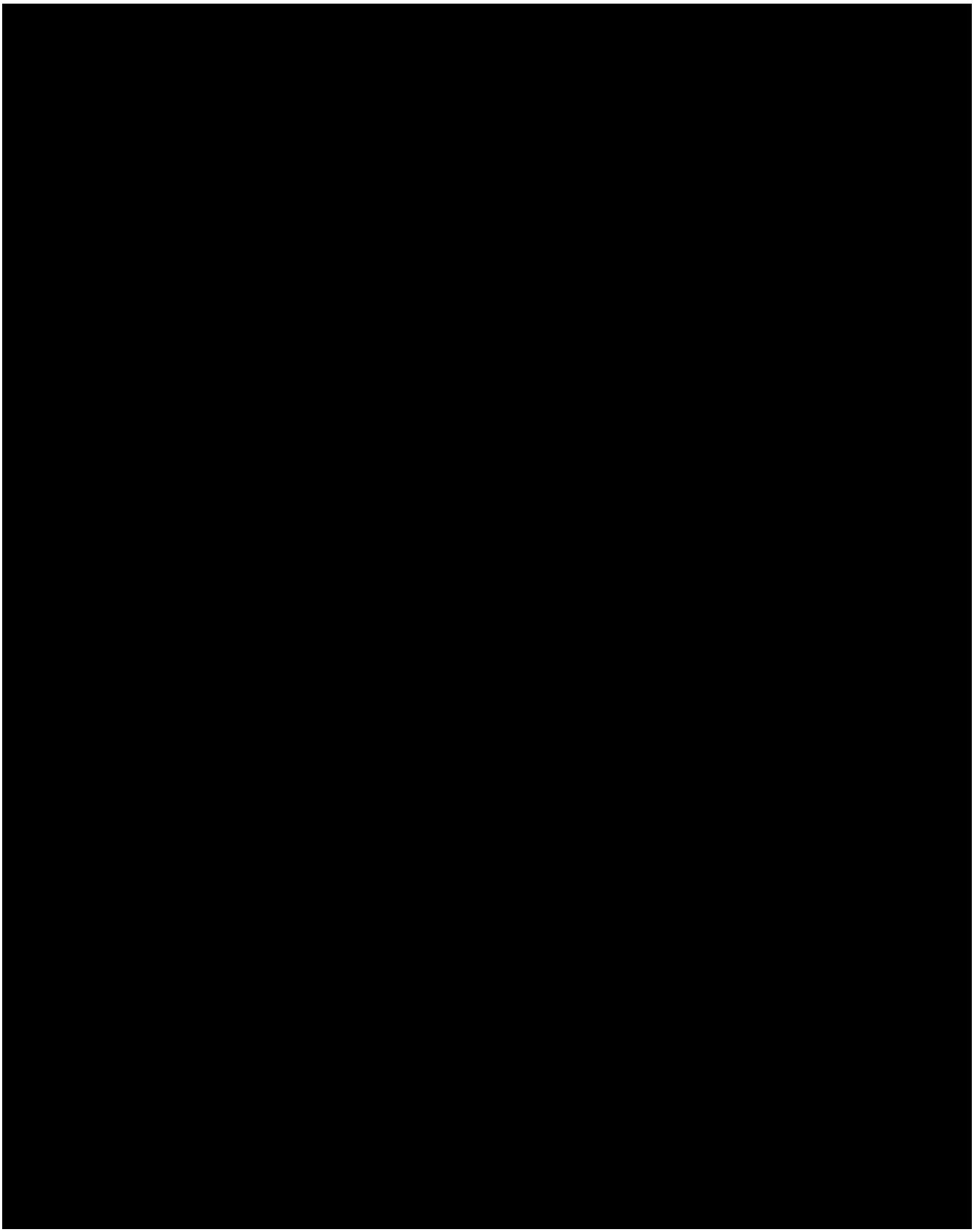
BACKGROUND

Trial in this matter was previously scheduled to begin on November 5, 2012.

[redacted]







The Testimony of Mr. Morrison

To rebut the opinions in the Bugay Supplemental Expert Report, Zydus submitted the February 12, 2013 Supplemental Expert Report of Harry Brittain Ph.D. and the February 12, 2013 Supplemental Expert Report of James Morrison. Morrison is an expert in "the area of FDA procedures and policy concerning drug regulatory issues and pharmaceutical manufacturers' compliance with FDA regulations and guidelines." February 12, 2013 Rebuttal Expert Report of James C. Morrison ("Morrison Report"), at ¶15. A copy of the Morrison Report is attached to the Rao Decl. as Ex. C.

Morrison's opinions are limited to the rebuttal of the opinions in the Bugay Supplemental Report [redacted] For example, to rebut Dr. Bugay's opinion [redacted], *see* February 15, 2013 Deposition Testimony of Dr. David Bugay, 211(18-19), Rao Decl. Ex. B and Bugay Supplemental Report, at ¶63, Rao Decl., Ex. A, Morrison states:

22. [redacted].

23. [redacted].

Morrison Report, at ¶¶22-23, Rao Decl., Ex. C.

Morrison also opines, in response to Dr. Bugay's opinions [redacted] (Bugay Supplemental Report, at ¶63, Rao Decl. Exh A), that:

28. [redacted].

29. [redacted]

[redacted].

30. [redacted]

Morrison Report, at ¶¶28-30, Rao Decl. Ex. C.

Morrison questions Dr. Bugay's opinions [redacted]:

[redacted]

Morrison Report, at ¶32.

Morrison also takes issue with Dr. Bugay [redacted]

[redacted]

[redacted]

Id., at 33, Rao Decl. Ex. C.

Contrary to Plaintiffs' argument, Morrison does not opine on matters outside the scope of his expertise. Instead, he uses his expertise to rebut certain of Dr. Bugay's opinions [redacted], a matter on which Dr. Bugay specifically opines. *See* Bugay Supplemental Report, at ¶63, Rao Decl., Ex. A.

ARGUMENT

MORRISON IS QUALIFIED TO OFFER THE OPINIONS HE WILL OFFER AT TRIAL, HIS TESTIMONY AND OPINIONS ARE RELIABLE AND RELEVANT AND THERE IS NO BASIS TO PRECLUDE HIM FROM OFFERING THESE RELEVANT OPINIONS AT TRIAL

Plaintiffs style their motion as a motion *in limine*, but Plaintiffs' motion is actually a *Daubert* motion seeking to exclude expert testimony. *See Daubert v. Merrill Dow Pharms.*, 509 U.S. 579 (1993). "Under the Federal Rules of Evidence, a trial judge acts as a 'gatekeeper' to ensure that 'any and all expert testimony or evidence is not only relevant but also reliable.'" *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008), quoting *Kannankeril v. Terminix*

Int'l Inc., 128 F.3d 802, 806 (3d Cir. 1997). In performing this "gatekeeper" function federal district court judges are guided by Federal Rule Evidence 702 and its stated requirements. *See Id.*, at 244 ("Rule 702 has three major requirements: (1) the proferred witness must be an expert, *i.e.*, must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact. Morrison easily satisfies each of the three requirements.

A. Morrison Is Qualified To Offer The Opinions He Will Offer at Trial

Plaintiffs argue that Morrison is not qualified to testify because he does not satisfy the definition of a person of ordinary skill in the art set forth in a prior expert report submitted by one of Zydus's other expert witnesses in regard to the skilled artisan for claim interpretation. (Memorandum of Law In Support of Plaintiffs' Motion *in Limine* to Preclude Expert Testimony by James Morrison ("Memorandum in Support"), at 5). Plaintiffs argument misses the point. Zydus does not contend that Morrison is qualified to testify on the intricacies of the chemistry underlying the claims at issue, or even patent invalidity, and Zydus is not proffering Morrison to testify or opine on these matters.

"Qualification requires 'that the witness possess specialized expertise.' . . . We have interpreted Rule 702's qualification requirement liberally. . . . We have held that a 'broad range of knowledge, skills, and training qualify an expert.'"

Pineda, 520 F.3d at 244. Indeed, the Third Circuit has specifically noted that "it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." *Id.* (quoting *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996)).

As detailed in the Morrison Report, Morrison was employed by the FDA from 1965-2003 with increasing responsibilities during that nearly 40 year period. *See* Morrison Report, at ¶¶3-12, Rao Decl. Ex. C. During that time period Morrison worked "on the enactment and implementation of the Hatch-Waxman Amendments to the Federal Food Drug and Cosmetic Act, including testifying at Congressional Hearings." *Id.* at ¶7. In addition to his work with the FDA, Morrison has written on numerous FDA issues, including issues related to the FDA's ANDA review process. *Id.* at ¶13. Morrison certainly possesses the knowledge, skill and training to qualify as an expert with respect to the matters set forth in his report. Plaintiffs' argument, that the opinions Morrison will offer are irrelevant to the matters at issue, does not change this fact. Of course, Plaintiffs own thinly disguised "*Daubert*" motion in limine, in fact, by sleight of hand, attempts to direct the Court away from the fact that Dr. Bugay clearly does not have the required expertise to opine [redacted]

[redacted] hoping the Court won't look "behind the curtains."

B. The Testimony and Opinions Morrison Will Offer at Trial Are Reliable

"An expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable. . . . While a litigant has to make more than a prima facie showing that his expert's methodology is reliable, we have cautioned that 'the evidentiary requirement of reliability is lower than the merits standard of correctness.'" *Pineda*, 520 F.3d at 247 (citations omitted). Plaintiffs argue that Morrison's opinions are unreliable because he states a number of baseless opinions. Plaintiffs are wrong, Morrison articulates the bases for his opinions and those opinions are reliable.

Plaintiffs argue that Morrison [redacted] (Memorandum in Support, at 7). In fact, Plaintiffs fail to fully quote the Morrison Report which actually states:

[redacted]

Morrison Report, at ¶28 (emphasis added). Thus, the basis for Morrison's opinion [redacted].

Plaintiffs also argue that Morrison speculates without any basis that: [redacted]" (Memorandum in Support, at 7). Morrison's opinion is not baseless. It is based upon his nearly 40 years of employment with the FDA and his knowledge of FDA procedures, as well as the actions FDA would take if an ANDA filer was underreporting actual median particle diameter, [redacted] in its tablets. In sum, Morrison's opinions, which are based on his wealth of experience in FDA matters, are undeniably reliable.

C. The Testimony and Opinions Morrison Will Offer at Trial Are Relevant

Plaintiffs argue that Morrison's opinions are not relevant to the matters at issue in this case. As the Third Circuit stated in *Pineda*:

> The rules of evidence embody a strong preference for admitting any evidence that may assist the trier of fact. . . Rule 702, which governs the admissibility of expert testimony, has a liberal policy of admissibility.

Pineda, 520 F.3d, at 243 (citations omitted); *see also*, *Sawyer v. Southwest Airlines, Co.*, 243 F. Supp. 2d 1257, 1266 (D.Kan. 2003) ("[T]he court must determine whether the proffered evidence would be helpful to the trier of fact. . . . Any doubts should be resolved in favor of admissibility.") (citations omitted); *Veloso v. Western Bedding Supply Co.*, 281 F. Supp. 2d 743, 750 (D.N.J. 2003) (the expert's testimony must assist the trier of fact but "[a]s with the expert's qualifications, the requirement of fit is not intended to be a high standard") (citations omitted). Morrison's opinions and the testimony he will offer will be helpful to the trier of fact, and are admissible.

Morrison's opinions and testimony go directly to a critical and hotly disputed issue in this case. [redacted]

[redacted]

Morrison also opines on whether the [redacted] by the FDA. Plaintiffs' do not contend that Morrison's opinion on this issue is irrelevant or will not assist the trier of fact. Indeed, the [redacted] is absolutely at issue and Morrison's opinion and anticipated testimony on this critical issue will certainly assist the trier of fact.

Plaintiffs also argue that Morrison's opinions and testimony will not assist the trier of fact because FDA does not concern itself with the particle size of enteric coated and finished coated granules. (Memorandum in Support, at 10).

[redacted]

[redacted]

February 25, 2013 Deposition of James C. Morrison, 49(5-17), excerpts of which are attached to the Rao Decl. as Ex. D. [redacted]

[redacted]

Morrison's opinions and testimony will assist the trier of fact. Moreover, Morrison is qualified to opine on these matters, as set forth in his expert report, and he provides sufficient bases for each opinion to make each opinion reliable. Thus, Morrison should not be precluded from testifying.

D. Plaintiffs Embellish Certain of the Case Law They Cite for the Proposition that the FDA Does not Have Expertise in Patent Matters

Plaintiffs, who obtained their own claim construction on the purported variability associated with laser diffractors of the time from the United States Pharmacopeia (which constitutes extrinsic evidence), now argue that "[c]ourts consistently recognize that FDA standards are separate and distinct from patent

standards and thus, have no relevance in patent cases." (Memorandum in Support, at 9). Plaintiffs cite *Scott v. Finney*, 34 F.3d 1058 (Fed. Cir. 1994) as support for this proposition. *Scott* involves an appeal of an award of priority by the Board of Patent Appeals and Interferences. *Id.* at 1059. In this case, the Court simply noted that "[t]esting for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings." *Id.* at 1063. *Scott* certainly does not stand for the proposition that FDA matters are never relevant in an ANDA litigation, [redacted].

Plaintiffs also cite *Andrx Pharms. Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002) and *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340 (D.N.J. 2003) for the proposition that the FDA lacks expertise in patent matters. Neither case discusses the FDA's expertise, or lack thereof, in regard to the matters on which Mr. Morrison provides testimony. In fact, both *Andrx* and *Dr. Reddy's* address the FDA's ability to police Orange Book listings. *Andrx Pharms.*, 276 F.3d, at 1378; *Dr. Reddy's* 302 F. Supp. 2d, at 362. Lastly, Plaintiffs cite *Hoffmann-La Roche v. Apotex, Inc.*, 2012 WL 1637736, at *9, n.9 (D.N.J. May 7,

2012). *Hoffmann La Roche* does state in a footnote that certain FDA guidelines were not relevant because they were not a component of the invention. Again, *Hoffmann La Roche* does not address the relevance of the FDA's view [redacted]. Thus, *Hoffmann La Roche* is inapposite.

CONCLUSION

For all the foregoing reasons Plaintiffs' Motion *In Limine* to Preclude Expert Testimony By James Morrison should be denied in its entirety and Mr. Morrison should be permitted to testify consistently with the opinions set forth in his February 12, 2013 expert report.

Dated: March 6, 2013

KELLEY DRYE & WARREN LLP

By: */s/ Vincent P. Rao II*

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CERTIFICATE OF SERVICE

I hereby certify that on March 6, 2013 I caused to be served a copy of the foregoing Defendants Zydus Pharmaceuticals, USA, Inc. and Cadila Healthcare's Memorandum in Opposition to Plaintiffs' Motion *in limine*, and the accompanying Declaration of Vincent P. Rao submitted therewith, dated March 6, 2013, on each interested party in this action in accordance with the electronic filing procedures of the United States District Court for the District of New Jersey via ECF and email on the following.

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Dated: March 6, 2013

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